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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 2728 | Date: June 14, 2013 |
| | Change Request 8292 |

SUBJECT: Ocular Photodynamic Therapy (OPT) with Verteporfin for Macular Degeneration

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after April 3, 2013, CMS will expand coverage of OPT with verteporfin for “wet” AMD. CMS is revising the requirements for testing to permit either optical coherence tomography (OCT) or FA to assess treatment response.

EFFECTIVE DATE: April 3, 2013

IMPLEMENTATION DATE: July 16, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|---|
| N | 32/300/Table of Contents |
| N | 32/300/Billing Requirements for Ocular Photodynamic Therapy (OPT) with Verteporfin |
| N | 32/300.1/Coding Requirements for OPT with Verteporfin |
| N | 32/300.2/Claims Processing Requirements for OPT with Verteporfin Services on Professional Claims and Outpatient Facility Claims |
| N | 32/300.3/Claims Processing Requirements for OPT with Verteporfin Services on Inpatient Facility Claims |
| N | 32/300.4/Medicare Summary Notice (MSN) and Remittance Advice (RA) Messages |

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined

in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

| | | | |
|--------------------|--------------------------|----------------------------|-----------------------------|
| Pub. 100-04 | Transmittal: 2728 | Date: June 14, 2013 | Change Request: 8292 |
|--------------------|--------------------------|----------------------------|-----------------------------|

SUBJECT: Ocular Photodynamic Therapy (OPT) with Verteporfin for Macular Degeneration

EFFECTIVE DATE: April 3, 2013

IMPLEMENTATION DATE: July 16, 2013

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) received a formal written request from the American Academy of Ophthalmology (AAO) to review and update National Coverage Determination (NCD) 80.3.1 (Ocular Photodynamic Therapy (OPT) with Verteporfin) since this coverage decision was from 2004, prior to the emergence of targeted anti-VEGF intravitreal treatments. These newer therapies have largely supplanted OPT as initial management of age-related macular edema (AMD) and OPT is largely relegated to patients in whom the newer therapies have failed. When the policy was first written, an initial fluorescein angiography (FA) was ordered to determine if the lesions were considered classic choroidal neovascular (CNV) lesions. Then the patients were followed monthly with additional FA to determine the need for retreatment. The NCD requirement for monthly follow-up FA for OPT with verteporfin is no longer supportable for these “end-stage” patients. (Note: The request specifies NCD 80.3.1 of the NCD Manual but corresponding changes also appear in NCDs 80.2, 80.2.1, and 80.3.)

B. Policy: Effective for claims with dates of service on and after April 3, 2013, CMS will expand coverage of OPT with verteporfin for “wet” AMD. CMS is revising the requirements for testing to permit either optical coherence tomography (OCT) or FA to assess treatment response.

OPT (CPT 67221/67225) with verteporfin (HCPCS J3396) continues to be a covered service when billed with ICD-9-CM 362.52 (Exudative Senile Macular Degeneration of Retina (Wet))/ICD-10-CM H35.32 (Exudative Age-related Macular Degeneration). For complete guidelines on claims processing please refer to the Claims Processing Manual, Chapter 32, Section 300. All other coverage and claims processing criteria continue to apply. Please also refer to the NCD manual, Chapter 1, section 80.3.1, 80.2, 80.2.1, and 80.3 for coverage criteria.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

| Number | Requirement | Responsibility | | | | | | | | | | |
|-----------|---|----------------|---|----------------------------|-----------------------|-----------------------|-----------------------|------------------------------|------------------|-------------|-------------|-------|
| | | A/B MAC | | D M E M A C | F I R E R | C A R E R | R H I E R | Shared-System Maintainers | | | | Other |
| | | A | B | | | | | H H H | F I S S | M C S | V M S | |
| 8292-04.1 | Effective for claims with dates of service on or after April 3, 2013, CMS will expand coverage of OPT (67221/67225) with verteporfin (J3396) for “wet” AMD (362.52/H35.32) Contractors shall accept and process claims for subsequent follow-up visits with either a fluorescein angiogram (FA), procedure code | | X | | | | X | | | | | |

| Number | Requirement | Responsibility | | | | | | | | | | | |
|-----------|--|----------------|---|-------------|----------------------------|----------------------------|---------------------------------|-------------|----------------------------------|-------------|-------------|-------------|-------|
| | | A/B MAC | | | D M E M A C | F I R I E R | C A R R I E R | R H I | Shared- System Maintainers | | | | Other |
| | | A | B | H H H | | | | | F I S S | M C S | V M S | C W F | |
| | 92235, or optical coherence tomography (OCT), procedure codes 92133 or 92134, prior to treatment. Please refer to the Pub. 100-03 NCD Manual, Chapter 1, Sections 80.3.1, 80.2, 80.2.1, and 80.3 for coverage policy. For claims processing instructions please refer to Pub. 100-04, Claims Processing Manual, Chapter 32, Section 300. | | | | | | | | | | | | |
| 8292-04.2 | Effective for claims with dates of service on or after April 3, 2013, contractors shall accept and process 13X and 85X claims for subsequent follow-up visits for OPT with verteporfin for wet AMD with either an FA test, procedure code 92235, or an OCT test, procedure codes 92133 or 92134, prior to treatment. | X | | | | X | | | | | | | |
| 8292-04.3 | Contractors shall not retroactively adjust claims from April 3, 2013 through the implementation of this CR. However, contractors may adjust claims that are brought to their attention. | X | X | | | X | X | | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | | | | | | | |
|-----------|--|----------------|---|-------------|----------------------------|----------------------------|---------------------------------|-------------|------------------|-------------|-------------|-------------|
| | | A/B MAC | | | D M E M A C | F I R I E R | C A R R I E R | R H I | Other | | | |
| | | A | B | H H H | | | | | F I S S | M C S | V M S | C W F |
| 8292-04.4 | MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within | X | X | | | X | X | | | | | |

| Number | Requirement | Responsibility | | | | | | | |
|--------|--|----------------|---|-------------|-------------|--------|---------------------------------|------------------|-------|
| | | A/B MAC | | | D M E | F I | C A R R I E R | R H H I | Other |
| | | A | B | H H H | M A C | | | | |
| | one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | | | | | | | | |

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
| | |

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Kimberly Long, 410-786-5702 or kimberly.long@cms.hhs.gov (Coverage) , Chuck Shih, 410-786-6671 or Chuck.Shih@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage) , Brian Reitz, 410-786-5001 or Brian.Reitz@cms.hhs.gov (Part B Claims Processing) , Cami DiCiacomo, 410-786-5888 or cami.digiacom@cms.hhs.gov (Part A Claims Processing) , Cynthia Thomas, 410-786-8169 or cynthia.thomas@cms.hhs.gov (Practitioner Part B)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

Section B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to

be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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300.4 - Medicare Summary Notice (MSN) and Remittance Advice (RA) Messages

300 – Billing Requirements for Ocular Photodynamic Therapy (OPT) with Verteporfin

(Rev.2728, Issued: 06-14-13-Effective: 04-03-13, Implementation: 07-16-13)

Ocular Photodynamic Therapy (OPT) is used in the treatment of ophthalmologic diseases; specifically, for age-related macular degeneration (AMD), a common eye disease among the elderly. OPT involves the infusion of an intravenous photosensitizing drug called Verteporfin, followed by exposure to a laser. For complete Medical coverage guidelines, see National Coverage Determinations (NCD) Manual (Pub 100-03) § 80.2 through 80.3.1.

300.1 - Coding Requirements for OPT with Verteporfin

Rev.2728, Issued: 06-14-13, Effective: 04-03-13, Implementation: 07-16-13)

The following are applicable Current Procedural Terminology (CPT) codes for OPT with Verteporfin:

67221- Destruction of localized lesion of choroid (e.g. choroidal neovascularization); photodynamic therapy (includes intravenous infusion)

67225- Destruction of localized lesion of choroid (e.g. choroidal neovascularization); photodynamic therapy, second eye, at single session (List separately in addition to code for primary eye treatment)

The following are applicable Healthcare Common Procedure Coding System (HCPCS) code for OPT with Verteporfin:

J3396- Injection, Verteporfin, 0.1 mg

300.2 - Claims Processing Requirements for OPT with Verteporfin Services on Professional Claims and Outpatient Facility Claims

(Rev.2728, Issued: 06-14-13, Effective: 04-03-13, Implementation: 07-16-13)

OPT with Verteporfin is a covered service when billed with ICD-9-CM code 362.52 (Exudative Senile Macular Degeneration of Retina (Wet)) or ICD-10-CM code H35.32 (Exudative Age-related Macular Degeneration).

Coverage is denied when billed with either ICD-9-CM code 362.50 (Macular Degeneration (Senile), Unspecified) or 362.51 (Non-exudative Senile Macular Degeneration) or their equivalent ICD-10-CM code H35.30 (Unspecified Macular Degeneration) or H35.31 (Non-exudative Age-Related Macular Degeneration).

OPT with Verteporfin for other ocular indications are eligible for local coverage determinations through individual contractor discretion.

Payment for OPT service (CPT code 67221/67225) must be billed on the same claim as the drug (J3396) for the same date of service.

Claims for OPT with Verteporfin for dates of service prior to April 3, 2013 are covered at the initial visit as determined by a fluorescein angiogram (FA) CPT code 92235 . Subsequent follow-up visits also require a FA prior to treatment.

For claims with dates of service on or after April 3, 2013, contractors shall accept and process claims for subsequent follow-up visits with either a FA, CPT code 92235, or optical coherence tomography (OCT), CPT codes 92133 or 92134, prior to treatment.

Regardless of the date of service of the claim, the FA or OCT is not required to be submitted on the claim for OPT and can be maintained in the patient's file for audit purposes.

300.3 - Claims Processing Requirements for OPT with Verteporfin Services on Inpatient Facility Claims

(Rev.2728, Issued: 06-14-13, Effective: 04-03-13, Implementation: 07-16-13)

Inpatient facilities shall report diagnosis code 362.52 (Exudative Senile Macular Degeneration of Retina (Wet)) or ICD-10-CM code H35.32 (Exudative Age-related Macular Degeneration) and procedure code 14.24 (Destruction of chorioretinal lesion by laser photocoagulation) and 99.29 (Infection or infusion of other therapeutic or prophylactic substance).

***300.4 - Medicare Summary Notice (MSN) and Remittance Advice (RA) Messages
(Rev.2728, Issued: 06-14-13, Effective: 04-03-13, Implementation: 07-16-13)***

The following message shall be used to notify beneficiaries and providers of denial situations that may occur:

*MSN 14.9: “Medicare cannot pay for this service for the diagnosis shown on the claim.”
(English version) or “Medicare no puede pagar por este servicio debido al diagnostic indicado en la reclamacion.” (Spanish Version)*

Claims Adjustment Reason Code B22: “This payment is adjusted based on the diagnosis.”